

525 Rec'd PCT/PTO 11 SEP 2000

Doc. No. 99914

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| In re patent |) | Before the Examiner |
|------------------------------|---|---------------------|
| application of: |) | |
| John P. Vanden Heuvel et al. |) | |
| C: -1 NL - 00/555 097 |) | Art Unit |
| Serial No. 09/555,987 |) | |
| Filed June 7, 2000 |) | |
| METHODS AND COMPOSITIONS FOR |) | September 5, 2000 |
| | , | September 5, 2000 |
| TREATING DIABETES |) | |

SUBMISSION OF SMALL ENTITY STATEMENT

Commissioner for Patents Washington, D.C. 20231

Sir:

Submitted herewith are the Verified Statements (Declarations) Claiming Small

Entity Status - Small Business Concern.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to the Commissioner for Patents, Washington, D.C. 20231 on September 5, 2000.

Jason J. Schwartz

Name of Registered Representative

Signature

Date of Signature

09/13/2000 ERIMANDO 00000052 09555987

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No fees are believed to be due at this time, however, should there be any fees deemed to be due, please charge our Deposit Account No. 23-3030.

Respectfully submitted

By:_____fush

Jason J. Senwartz, Reg. No. 43,910

Woodard, Emhardt, Naughton,

Moriarty & McNett

Bank One Center/Tower

111 Monument Circle, Suite 3700

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PTO/SB/11 (12-97)

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Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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| STATEMENT CLAIMING SMALL ENTITY STATUS | Dock † Number (Optional) |
|--|---|
| (37 CFR 1.9(f) & 1.27(d))NONPROFIT ORGANIZATION | 7024-465 |
| Applicant, Patent e, or Identifier: JOHN P. VANDEN HEUVEL, et al. | |
| Application or Patent No.: 09/555,987 | |
| Filed or Issued; June 7, 2000 | |
| Title: METHODS AND COMPOSITIONS FOR TREATING DIABETES | |
| METIODS AND CONFOSHIONS FOR IREATING DIABETES | |
| I hereby state that I am an official empowered to act on behalf of the nonprofit organization I | |
| NAME OF NONPROFIT ORGANIZATION The Penn State Research Foundation | |
| | |
| University Park, PA 16802 | |
| TYPE OF NONPROFIT ORGANIZATION: | |
| UNIVERSITY OR OTHER INSTITUTION OF HIGHER EDUCATION | |
| TAX EXEMPT UNDER INTERNAL REVENUE SERVICE CODE (26 U.S.C. 501(a) and 501(c)(3)) | |
| LI NONPROFIT SCIENTIFIC OR EDUCATIONAL UNDER STATUTE OF STATE OF THE UNITED STATE (NAME OF STATE) | S OF AMERICA |
| (NAME OF STATE) (CITATION OF STATUTE) | |
| ☐ WOULD QUALIFY AS TAX EXEMPT UNDER INTERNAL REVENUE SERVICE CODE (26 U.S.C. 50 IF LOCATED IN THE UNITED STATES OF AMERICA | 1(a) and 501(c)(3)) |
| WOULD QUALIFY AS NONPROFIT SCIENTIFIC OR EDUCATIONAL UNDER STATUTE OF STATE STATES OF AMERICA IF LOCATED IN THE UNITED STATES OF AMERICA | OF THE UNITED |
| (NAME OF STATE) | |
| (CITATION OF STATULE) | |
| I hereby state that the nonprofit organization identified above qualifies as a nonprofit org 1.9(e) for purposes of paying reduced fees to the United States Patent and Trademark Office r described in: | |
| the specification filed herewith with title as listed above. | |
| the application identified above. the patent identified above. | |
| I hereby state that rights under contract or law have been conveyed to and remain regarding the above identified invention. If the rights held by the nonprofit organization are concern, or organization having rights in the invention must file separate statements as to that no rights to the invention are held by any person, other than the inventor, who would inventor under 37CFR 1.9(c) If that person made the invention, or by any concern which business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e). | not exclusive, each individual, neir status as small entities and not qualify as an independent |
| Each person, concern, or organization having any rights in the invention is listed below: | |
| no such person, concern, or organization exists. ach such person, concern, or organization is listed below. | |
| Joint ownership with Purdue Research Foundation, Office of Technology Commercial 1291 Cumberland Avenue, West Lafayette, IN 47906 | alization, |
| l acknowledge the duty to file, in this application or patent, notification of any char entitlement to small entity status prior to paying, or at the time of paying, the earliest of the fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28) | Issue fee or any maintenance |
| NAME OF PERSON SIGNING Thomas J. Monahan (Reg. No. 29,835) | |
| TITLE IN ORGANIZATION OF PERSON SIGNING University Legal Counsel, Intellect | ual Property Office |
| ADDRESS OF PERSON SIGNING 113 Technology Center, University Park, PA 1680 | 2-7000 |
| SIGNATURE DATE August | 31, 2000 |
| | |

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FCC, U.S., DEPARTMENT OF COMMERCE ik and Tie Under the Persentage Restation Act of 1995, no versions are required to recessed to a so THE RESIDENCE CONTROL OF THE PERSON STATEMENT CLAIMIN SMALL ENTITY STATUS Docket Number (Optional) (37 CFR 1.8(f) & 1.27(d))—NONPROFIT DRGANIZATI N 7024-465/PUR99 John P. Vanden Heuvel Applicant, Patentee, or Identifier, 09/555,987 Application or Patent No.: June 7, 2000 Filed or lessued: TRE: METHODS AND COMPOSITIONS FOR TREATING DIABETES) hereby state that I am an official empowered to act an behalf of the nonprofit organization identified below.

NAME OF NONPROFIT ORGANIZATION Purdue Research Foundation ADDRESS OF NONPROFIT ORGANIZATION Office of Technology Commercialization, 1291 Cumherland Avenue, Wost Lafayette, IN 47905 Type of nonprofit organization: D LINNERSITY OR OTHER INSTITUTION OF HIGHER EDUCATION TAX EXEMPT UNDER INTERNAL REVENUE SERVICE CODE (28 U.S.C. 501(a) and 501(c)(3)) MONPROFIT SCIENTIFIC OR EQUICATIONAL UNDER STATUTE OF STATE OF THE UNITED STATES OF AMERICA (NAME OF STATE (CITATION OF STATUTE) WOULD QUALIFY AS TAX EXEMPT UNDER INTERNAL REVENUE SERVICE CODE (28 U.S.C. \$01(a) and \$61(c)(3)) IF LOCATED IN THE UNITED STATES OF AMERICA I hereby state that the compactic organization identified above qualifies as a nonprofit organization as defined in 37 CFR (1.9(a) for purposes of paying reclused fees to the United States Patent and Trademark Office recarding the inventor described the specification filed herewith with title as listed above. the application identified above. the patent identified above. I hereby state that rights under contract or last have been conveyed to and remain with the nonprofit organization regarding the above identified invention. If the rights held by the conprofit organization are not exclusive, each individual concern, or organization having rights in the invention must be separate statements as to their citates as entail entities and interior interior or organization having rights in the invention must be supported, other than the invention, who would not qualify as an independent invention wider 37 CFR 1.9(c) if that person made the invention, or by the concern which would not qualify as a small business concern under 37 CFR 1.9(c). Each person, concern, or organization having any rights in the invention is listed below: Circ such person, concern, or organization exists.

Figure such person, concern, or organization is fissed below. The Penn State Research Foundation,
The Penn State University, 111 Technology Center, University Park, PA
16802-7000 l actinowlaring the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the entities of the tasue less or any maintaisance feet due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b)) Brace L. Pershing NAME OF PERSON SIGNING TITLE IN ORGANIZATION OF PERSON SIGNING COTPORATE Secretary Office of Technology address of Person Signing Commettialization 1291 Cumberland Ave avette IN 47906 SIGNATURE _ 130100 DATE

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Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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7024465PUR99 Attorney Docket Number **DECLARATION FOR UTILITY OR** John P. Vanden Heuve First Named Inventor **DESIGN** PATENT APPLICATION COMPLETE IF KNOWN (37 CFR 1.63) **Application Number** 09 /555,987 June 7, 2000 Filing Date Declaration Declaration Submitted after Initial Submitted OR **Group Art Unit** Filing (surcharge (37 CFR 1.16 (e)) with Initial Filing Examiner Name required)

| As a below named inventor, I hereby declare that: | | | | | | | | | | | |
|--|---|--|-------------------------|--|---------|--|--|--|--|--|--|
| My residence, post office a | address, and citizenship are | as stated below next to m | у пате. | | | | | | | | |
| I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: | | | | | | | | | | | |
| METHODS AND COMPOSITIONS FOR TREATING DIABETES | | | | | | | | | | | |
| the specification of which (Tide of the Invention) | | | | | | | | | | | |
| is attached hereto | | | | | | | | | | | |
| OR X was filed on (MM/D) | pmm [12/11/19 | 98 as Unit | ed States Applica | tion Number or PCT Intern | ational | | | | | | |
| Application Number DCT | /uco 9 / 26 / 40 | | | | | | | | | | |
| Application Number PCT/ | | as amended on (MM/DD/ | - | (if appli | cable). | | | | | | |
| I hereby state that I have re amended by any amendmen | nt specifically referred to ab | ove. | пшнеа ѕреспсаво | n, including the claims, as | | | | | | | |
| I acknowledge the duty to di | sclose information which is | material to patentability as | s defined in 37 CF | R 1.56. | | | | | | | |
| I hereby claim foreign prioriticetificate, or 365(a) of any America, listed below and has or of any PCT international approximation of the second sec | PCT international application also identified below, by | in which designated at leachecking the box, any fore | ast one country or | other than the United State patent or inventor's certifications. | es of | | | | | | |
| Prior Foreign Application Number(s) | Country | Foreign Filing Date (MM/DD/YYYY) | Priority Not Claimed | Certified Copy Attach YES NO | ed? | | | | | | |
| US98/26469 | PCT | 12/11/1998 | 0000 | 0000 | | | | | | | |
| | ion numbers are listed on a | | | | | | | | | | |
| I hereby claim the benefit ur | | | l application(s) lis | ted below. | | | | | | | |
| Application Number(: | 12/12/19 | 97 | | nal provisional applicaters are listed on a | ion | | | | | | |
| | | | supple | mental priority data she B/02B attached hereto. | | | | | | | |

(Page 1 of 2)

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DECLARATION

R gist r d Practiti ner Inf rmation (Supplem ntal Sh t)

| Name | Registration | Name | Registration |
|-------------------------|--------------------|------|--------------|
| | Number | | Numb r |
| Harold R. Woodard | 16,214 | | |
| C. David Emhardt | 18,483 | | • |
| Joseph A. Naughton, Jr. | 19,814 | | , |
| John V. Moriarty | 26,207 | | |
| John C. McNett | 25,533 | | |
| Thomas Q. Henry | 28,309 | | |
| James M. Durlacher | 28,840 | | |
| Charles R. Reeves | 28,750 | | |
| Vincent O. Wagner | <u>29,596</u> | | j |
| Steve Zlatos | 30,123 | | |
| Spiro Bereveskos | 30,821 | | İ |
| William F. Bahret | 31,087 | | |
| Clifford W. Browning | 32,201 | | |
| R. Randall Frisk | 32,221 | | |
| Daniel J. Lueders | 32,581 | | |
| Kenneth A. Gandy | 33,386 | | |
| Timothy N. Thomas | 35,714 | | |
| Kerry P. Sisselman | 37,237 | | j . |
| Kurt N. Jones | 37,996 | | |
| John H. Allie | 39,088 | | |
| Holiday W. Banta | 40,311 | | |
| Troy J. Cole | 35,102 | | |
| L. Scott Paynter | 39,797 | | |
| J. Andrew Lowes | 40.706 | | i |
| Charles J. Meyer | 41,996 | | |
| Darrin Wesley Harris | 40,636 | | |
| Matthew R. Schantz | 40,800 | | |
| Gregory B. Coy | 40,967 | • | |
| Lisa A. Hiday | 40,036 | | |
| John V. Daniluck | 40,581 | | |
| Christopher A. Brown | 41,642 | • | |
| C. John Brannon | 44,557 | | |
| Jason J. Schwartz | 43,910 | • | |
| Arthur J. Usher IV | 41,359 | | |
| Douglas A. Collier | 43,556 | | |
| Brad A. Schepers | 45,431 | | |
| R. Craig Tucker | 45,165 | | |
| Scott J. St vens | | | |
| James B. Myers | 29,446 | | |
| John M. Bradshaw | 42,021 D 46 570 | | |
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Utility or Design Patent Application

I hereby claim the benefit under 35 U.S.C. 120 of any United States application(s), or 385(c) of any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT international application in the manner provided by the first paragraph of 35 U.S.C. 112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

| , U | .S. Pai | rent Application | | PCT Paren | t | | | iling Date | 7 | | arent Patent Number (if applicable) | | |
|-------------------------|--------------------------------|---|----------------------------|---|--|--------------------------------|---------------------------------|---|-----------|---------------------------------|--|--|--|
| 60/069 PCT/US | | 469 | | • | | | | 1997 1998 | | | | | |
| Additiona | I U.S. or | PCT international ap | plicat | lon numbers a | re listed on | a supp | ement | al priority dat | sheet i | TO/SB/ | 02B attacher | l hereto | |
| As a named im | ventor, l | hereby appoint the fi onnected therewith: | | ng registered p Customer Nurr <i>OR</i> Registered pra | nber | s) to pı | osecute | this applicat | ion and t | o transa | ct all busines Place Cu Number B | s in the Pater stomer ar Code | |
| | Nan | 10 | | Regist | tration nber | | | Nar | | | | istration lumber | |
| Kenneth | ı A, | Gandy | | #33,386 | | | | | | | | | |
| XX Additional | registere | d practitioner(s) nan | ned on | supplemental | Registered | d Pract | itioner la | nformation sh | eet PTO | /SB/02C | attached he | reto | |
| Direct all corr | | ence to: 🔲 Cu | stome | er Number ode Label | | | | | | | | dress below | |
| Name · | _Ken | neth A. Gan | <u>dy</u> | | | | | | | ··· | • | | |
| Address | WOO | DARD EMHARD | T N | AUGHTON | MORIA | RTY | & MC | NETT | | | | | |
| Address | Ban | k One Cente | r/T | ower, 11 | l Monu | ımen | t Ci | rcle, S | uíte | 3700 | | | |
| City | | ianapolis <u>.</u> | | | | T | | | | 4620 | | | |
| Country | USA | | | Telephon | e (317 | 7) 6 | 34-3 | 456 | Fax | (31 | (317) 637-7561 . | | |
| punishable by | fine or ir | I statements made if urther that these aprisonment, or bot t issued thereon. | herein staten h, und | of my own k ments were m der 18 U.S.C. | nowledge a ade with the 1001 and | are true ne knom that su | e and the Medge uch willf | nat all statem that willful fa ul false state | ents ma | de on in ments a nay jeop | nformation a and the like a ardize the v | nd belief are so made are alidity of the | |
| Name of Sc | ie or F | irst Inventor: | | | | | petitio | n has been | filed for | r this un | signed inve | entor | |
| Gl | ven Nar | ne (first and midd | e lif e | inyl) | | | | Family | Name | or Sum | ame | | |
| | John | 1 P. | | | | V. | ander | n Heuve | | | | | |
| Inventor's Signature | | John P | 1/_ | X | 1 | | | | • | | Date | 7/18/00 | |
| Residence: C | dence: City Port Matilda State | | | | | PA |) untry | USA | | | Citizenship | US | |
| Post Office Ad | Idress | 101 James | Hil | ll Road | | | | | , | | | | |
| Post Office Ac | Idress | | | | | | | | | | | | |

[Page 2 of 2]

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U,S.A.

Country

supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto

Port Matildia PA

 $oxed{\Omega}$ Additional inventors are being named on the 1





Please type a plus sign (+) inside this box -> +

valid OMB control number.

DECLARATION

ADDITIONAL INVENTOR(S) Supplemental Sheet Page ___ of ___

| | | | | | | | | | | | | |
|-------------------------|--|---|------|------------------------|---------|---------------------------------------|-------------|-------------|--------|---------|--|--|
| Name of Addition | nal Joint Inventor, if an | y: | | _ A pe | tition | has been filed | for this | unsign | ed inv | entor | | |
| Given Nar | me (first and middle (if any) |) | | Family Name or Surname | | | | | | | | |
| Martha A, | | | | Belury | | | | | | | | |
| Inventor's Signature | Martha | α | _Re | Elling | | | | Date |] | 7/26/00 | | |
| Residence: City | Redmond | State | WA W | Coun | 17 | USA | | Citizensi | Np 1 | US | | |
| Poet Office Address | 9010 172nd Avenue NE | | | | | | | | | | | |
| Post Office Address | | | · | | | | | | | | | |
| City | Redmond | State | WA | ZIP | 9 | 98052 c | ountry | USA | | | | |
| Name of Addition | nal Joint Inventor, if an | I Joint Inventor, if any: A petition has been filed for this unsigned inventor | | | | | | | | | | |
| Given Nar | Given Name (first and middle [if any]) Family Name or Sumame | | | | | | | | | | | |
| Louise W, | Peck . | | | | | | | | | | | |
| Inventor's Signature | | | | | | | <u> </u> | Dat | le | | | |
| Residence: City | Moscow . | State | ID | Coun | try | USA | | Citizer | ship | US | | |
| Post Office Address | 430 E. Lewis St | reet | | | | | | | | | | |
| Post Office Address | | | | | | · · · · · · · · · · · · · · · · · · · | | ··········· | | | | |
| City | Moscow | State | ID | z | IP | 83843 | Count | ן עז | SA_ | | | |
| Name of Addition | nal Joint Inventor, if an | iy: | { | □ A pa | rtitior | n has been filed | for this | ı unsign | ed inv | rentor | | |
| Given Na | me (first and middle (if any) | 0 | | | | Family Nam | e or S | umame | | | | |
| | | | | | | | | | | | | |
| Inventor's Signature | | | | | | | | Da. | te | | | |
| Residence: City | | State | | Cour | itry | • | | Citizer | nship | | | |
| Post Office Address | | | | | | | | | | | | |
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DECLARATION

ADDITIONAL INVENTOR(S)
Supplemental Sheet
Page ___ of ___

| | | | | <u> </u> | | | , | | <u> </u> | | | |
|-------------------------|-------------------------------|---------------------------------------|------|--|--------|--|---------------|-------------|------------|---------|----------|--|
| Name of Addition | nal Joint Inventor, if an | y: | · | A petition has been filed for this unsigned inventor | | | | | | | | |
| | ne (first and middle (if any | | | Family Name or Surname | | | | | | | | |
| Martha A, | | | | Belury | | | | | | | | |
| inventor's Signature | | | | | | | | | Date | | | |
| Residence: City | Redmond | State | WA | | Countr | | USA | | Citizens | | US | |
| Poet Office Address | 9010 172nd Avenue NE | | | | | | | | | | | |
| Post Office Address | | · · · · · · · · · · · · · · · · · · · | | | | | | | | | | |
| City | Redmond | State | WA | | ZIP | 9 | 8052 | Countr | USA | | | |
| Name of Addition | I Joint Inventor, if any: | | | | | | | | | | entor | |
| Given Nar | me (first and middle [If any) |) | | Family Name or Surname | | | | | | | | |
| Louise W, | Peck . | | | | | | | | | | | |
| Inventor's Signature | Louise W | Pu | A | | | | | | Da | te | 7/24/200 | |
| Residence: City | Moscow . | State | ID - | | Countr | <u>, </u> | USA | | Citizer | nship | US | |
| Post Office Address | 430 E. Lewis St | reet | | | | | | | | | | |
| Post Office Address | | | | | | | | | | | | |
| City | Moscow | State | ID | | ZIP | | 83843 | Cou | ntry [| ISA | | |
| Name of Addition | nal Joint Inventor, if ar | ıy: | | | A pet | tion | has been file | ed for th | nis unsigr | ned inv | rentor | |
| Given Na | me (first and middle (if any | D | | | | | Family Na | me or | Sumame | | | |
| | | | | | | | | | | | | |
| Inventor's Signature | | | | | | | | | Da | ite | | |
| Residence: City | | State | | | Countr | <u>, </u> | | | Citize | nship | | |
| Post Office Address | | | | | | | | | | | | |
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(Page 1 of 2)

Additional provisional application

numbers are listed on a supplemental priority data sheet PTO/SB/02B attached heret.

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| ☐ Additional | Additional U.S. or PCT international application numbers are listed on a supplemental priority data sheet PTO/SB/028 attached hereto. | | | | | | | | | | |
| As a named inventor, I hereby appoint the following registered practitioner(s) to prosecute this application and to transact all business in the Pa and Trademark Office connected therewith: Customer Number Customer Number Customer Number Registered practitioner(s) name/registration number listed below Label here | | | | | | | | | | s in the Pater Nomer or Code | |
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DECLARATION

ADDITIONAL INVENTOR(S) Supplemental Sheet Page ___ of ___

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|-------------------------|--|-------|--------------|---------------|------------------------|------------------|--|------------|---------|--------------|--|--|--|
| Name of Additio | Name of Additional Joint Inventor, if any: | | | | | | A petition has been filed for this unsigned inventor | | | | | | |
| Given Na | me (first and middle (if any) |) | | | Family Name or Surname | | | | | | | | |
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| Inventor's Signature | | | | | | Date | | | | | | | |
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| Name of Additio | nal Joint Inventor, if an | y: | | | A petitio | on has been file | d for th | is unsig | ned inv | entor | | | |
| Given Na | me (first and middle [if any] |) | | | | Family Na | me or : | Sumame | | | | | |
| Louise W, | | | | | Peck . | | | | | | | | |
| inventor's Signature | | | | | | | | Di | ite | | | | |
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Attorney Docket Number 7024465PUR99 **DECLARATION FOR UTILITY OR** John P. Vanden Heuvel First Named Inventor **DESIGN** PATENT APPLICATION COMPLETE IF KNOWN (37 CFR 1.63) **Application Number** Filing Date □ Declaration ☐ Declaration OR Submitted Submitted after Initial Group Art Unit Filing (surcharge (37 CFR 1.16 (e)) with Initial Filing **Examiner Name** required)

| As a below named invento | or, I hereby declare that | : | | | | | | | | | | |
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| My residence, post office ad | dress, and citizenship ar | e as stated below next to my | y name. | | | | | | | | | |
| I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: | | | | | | | | | | | | |
| METHODS AND | METHODS AND COMPOSITIONS FOR TREATING DIABETES | | | | | | | | | | | |
| the specification of which | σ | ide of the Invention) | | | | | | | | | | |
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| I hereby state that I have rev | ewed and understand the | contents of the above iden | tifled specificatio | n, including the c | laims, as | | | | | | | |
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| I hereby claim foreign priority certificate, or 365(a) of any P America, listed below and have or of any PCT international app | CT international applicate also identified below, by | ion which designated at lea checking the box, any lore | ist one country ign application fo | other than the Ui | nited States | s of | | | | | | |
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| As a named in | ventor. I | hereby appoint i connected there | the follows | ing registered Customer Nu OR | mber | s) to prosecu | te this application | on and t | o trans | Place Cus Place Cus Number Ba Label h | s in the Pater Homer or Code | |
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